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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,010	03/24/2001	Mark B. Lyles	068986.0105	5741

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EXAMINER

JOYNES, ROBERT M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 03/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/817,010

Applicant(s)

LYLES, MARK B.

Examiner

Robert M. Joynes

Art Unit

1615

-- Th MAILING DATE of this communication appears on th cover sh et with the correspondenc address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 3-19, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 2, 20-23 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-19 and 24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

### **DETAILED ACTION**

Receipt is acknowledged of applicant's Amendment and Request for Continued Examination filed on December 31, 2002. The Request for Continued Examination was improper for this application because the prosecution of this application was not closed at the time of filing. A letter stating the Request was improper was mailed on March 12, 2003.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5 and 7-19, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Lyles et al. (US 5621035). Lyles teaches a composition comprising about 1% to about 50% by weight alumina, about 50% to about 98% by weight silica, and about 1% to about 5% by weight boron (Col. 3, lines 14-22). The composition further comprises silicon carbide (Col. 12, Claim 13). The density of the composition ranges from 4 lb./ft<sup>3</sup> to 62 lb./ft<sup>3</sup> (Col. 3, lines 30-63). The composition is also highly porous (Col. 3, lines 30-63). Carbon fibers are also added to the composition (Col. 4, lines 37-67).

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Claims 1, 3-5 and 7-19, 24 and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Lyles et al. (US 5951295). Lyles teaches a composition comprising about 1% to about 50% by weight alumina, about 50% to about 98% by weight silica, and about 1% to about 5% by weight boron (Col. 3, lines 19-27). The composition further comprises silicon carbide (Col. 15, Claim 16). The density of the composition ranges from 4 lb./ft<sup>3</sup> to 62 lb./ft<sup>3</sup> (Col. 3, line 44 – Col. 4, line 18). The composition is also highly porous (Col. 3, line 44 – Col. 4, line 18; See also claims 12, 22, and 25). Carbon fibers are also added to the composition (Col. 4, line 60 – Col. 5, line 21). Lyles further teaches that the composition comprises zirconium fibers in addition to the already mentioned fibers (Col. 9, lines 9-15; col. 10, lines 1-8).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 5 and 7-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyles et al. (US 5621035). The teachings of Lyles are discussed above. Lyles does not teach the exact porosity of the composition or the silicon dioxide content on surface of the composition.

While the reference does not teach the complete concentration range or porosity, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a composition comprising silica, alumina and boron with a specific porosity and density. It is the position of the examiner that prior art has obtained this result i.e., a composition with a wide range of density and is highly porous comprising silica, alumina and boron, and that no criticality is seen in applicant's particular porosity ranges or silicon dioxide content. Any distinction is a matter of degree and not of kind.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-5 and 7-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyles et al. (US 5951295). The teachings of Lyles are discussed above. Lyles

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does not teach the exact porosity of the composition or the silicon dioxide content on surface of the composition.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a composition comprising silica, alumina and boron with a specific porosity and density. It is the position of the examiner that prior art has obtained this result i.e., a composition with a wide range of density and is highly porous comprising silica, alumina and boron, and that no criticality is seen in applicant's particular porosity ranges or silicon dioxide content. Any distinction is a matter of degree and not of kind.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lyles et al. (US 5621035) or Lyles et al. (US 5951295) in view of Markkula et al. (US 6063395). The teachings of the Lyles references are discussed above. Neither Lyles reference teaches the incorporation of a drug.

Markkula teaches an implant drug delivery device comprising silica and a therapeutic active agent (Col. 10, Claims 1-12).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate an active agent in the porous composition.

One of ordinary skill in the art would have been motivated to do this to delivery subcutaneously a drug at a substantially constant rate for a prolonged period of time.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

Applicants' arguments filed December 31, 2002 has been fully considered but are not found to be persuasive. Applicants' argue that the prior art does not teach or suggest a porous composition having (i) a density as low as 3.5 pounds per cubic foot comprising up to 100% silica wherein the silica comprises up to about 50% cristobalite, (ii) with up to about 50% of the exposed surface area being silicon dioxide.

The Examiner would like to first point out that the components of the composition and the method of making the composition are the same. Applicants state in the instant Specification that the process of making the composition is taught in U.S. Patent No. 5,951,295. The components or main ingredients of the composition appear to be exactly the same, silica and alumina. Therefore, the Examiner fails to see the difference between the instant claimed composition and the prior art composition when the components and method of making the composition are the same.

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More specifically, the density of the prior art is from 4 lbs/ft.<sup>3</sup> to 62 lbs.t.<sup>3</sup> and the instant claims recite a density of at least about 3.5 lbs./ft.<sup>3</sup>. Again, the Examiner fails to see the difference of a lower limit of "about 3.5 lbs/ft.<sup>3</sup>" and 4 lbs/ft.<sup>3</sup>. Any distinction is a matter of degree and not of kind.

As for the concentration of cristobalite, the instant claims recite that the silica comprises up to about 50% cristobalite. This limitation reads on a composition of silica that has 0% cristobalite as well as a composition having up to about 50% cristobalite. Again, the Examiner fails to see the difference between the instant claimed composition and the prior art composition when the components and method of making the composition are the same.

As for the concentration of the silicon dioxide on the exposed surface of the composition, the instant claims read that the exposed surface comprises at least about 50% silicon dioxide. Upon a careful examination of the instant Specification and the prior art, it appears that the components of the composition are the same as well as the method of making said composition. Reciting a characteristic of the same composition that was originally not recited in the prior art does not lend itself to patentability. It is still the same composition produced by the same method. It appears that the same composition is produced in the instant application as is produced in the prior art and by the same method. The recitation of the silicon dioxide content on the exposed surface appears to be a characteristic not recited in the prior art but this characteristic does not render the claims patentable over the prior art.



For the reasons stated above, the rejections recited in the Office Action dated July 3, 2002 is maintained.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes  
Patent Examiner  
Art Unit 1615  
March 13, 2003

  
THURMAN K. PAGE  
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